PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 : A61F 2/06	A2	(11) International Publication Number: WO 88/ 06026 (43) International Publication Date: 25 August 1988 (25.08.88)

(21) International Application Number: PCT/EP88/00115

(22) International Filing Date: 17 February 1988 (17.02.88)

(31) Priority Application Number: 19405 A/87

(32) Priority Date: 17 February 1987 (17.02.87)

(33) Priority Country: IT

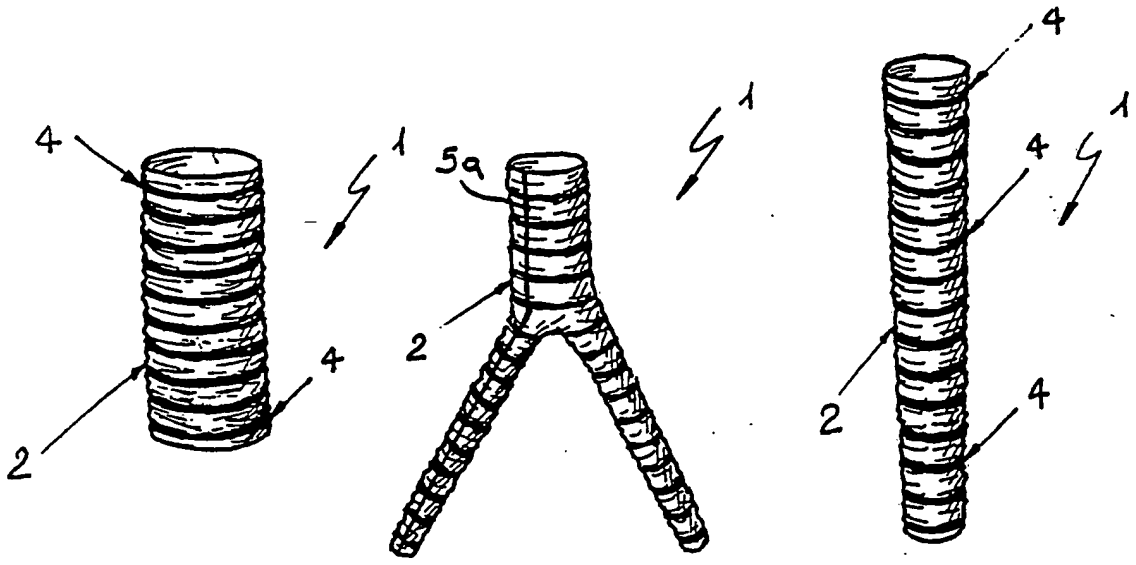
(71)(72) Applicant and Inventor: ARPESANI, Alberto [IT/IT]; Piazza S. Angelo, 1, I-20121 Milano (IT).

(74) Agent: RAPISARDI, Mariacristina; Studio Tecnico Legale Rapisardi, Largo V Alpini 15, I-20145 Milano (IT).

(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: INTERNAL PROSTHESIS FOR THE SUBSTITUTION OF A PART OF THE HUMAN BODY PARTICULARLY IN VASCULAR SURGERY



(57) Abstract

Internal prosthesis for the substitution of a part of the human body particularly in vascular surgery, which has a body (2) with a substantially tubular configuration, made of plastic material tolerated by the human body and suitable for being associated by its free ends, through a suture, to the ends of one or more arteries; advantageously the body defining the prosthesis is radiopaque so that it can be easily detected by means of an X-ray apparatus.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	ML	Mali
AU	Australia	GA	Gabon	MR	Mauritania
BB	Barbados	GB	United Kingdom	MW	Malawi
BE	Belgium	HU	Hungary	NL	Netherlands
BG	Bulgaria	IT	Italy	NO	Norway
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic			SE	Sweden
CG	Congo	KR	Republic of Korea	SN	Senegal
CH	Switzerland	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
DE	Germany, Federal Republic of	LU	Luxembourg	TG	Togo
DK	Denmark	MC	Monaco	US	United States of America
FI	Finland	MG	Madagascar		

INTERNAL PROSTHESIS FOR THE SUBSTITUTION OF A PART OF THE HUMAN BODY PARTICULARLY IN VASCULAR SURGERY.

Technical field:

This invention relates to an internal prosthesis for the substitution of a part of the human body, particularly in vascular surgery.

Background Art:

As it is known, vascular surgery together with orthopedic surgery is the one which mostly profited by the introduction of prosthetic materials.

The first substitutions of arterial trunci go back to few decades ago, when the homologous graft technique was introduced, i.e. the substitution of the injured or ill part with a similar segment taken from a corpse.

Preserved human arteries had been for many years the substitutive material of choice; however, the difficulties related to the timely finding of arterial parts of special size and shape, the need to depend on "arteries banks", and the frequent technical problems related to anastomosis caused a gradual reduction in the field of their application when substitutive plastic materials were introduced on the market.

The ideal material for vascular prosthesis should include essentially the following features: it should not have any toxic, allergic or carcinogenic action, it should be

logically inert, i.e. it should be well tolerated by the host organism, it should have a high degree of elasticity, a good porosity and high permeability to migrating cells.

The last quality is absolutely necessary so that the host fibroblasts can penetrate the thickness of the prosthesis wall by fixing the same to the surrounding tissues.

Similarly, inside the channel, the cells coming from the blood can adhere to the surface and form a layer defined as neointima.

Furthermore, it is necessary that the prosthesis material can be submitted to the various sterilization procedures without losing its properties and that it can be also easily shaped by means of scissors.

Sometimes it happens that, after a shorter o longer period of time, the prosthesis detaches in the suture thus causing the formation of a scar tissue that by collapsing due to the blood pressure causes a pseudoaneurism and causes the prosthesis end to come off the artery end to which it was associated.

In this type of pathology, a layer of expanded scar tissue forms around the prosthesis, thereby the arterial blood laminar flow becomes vortical thus causing a thrombi stratification within the scar tissue itself, which may be a risk for the patient.

Currently, the sole analysis techniques available to

cular surgeons in order to detect the prosthesis detachment in the suture are x-ray, echography, angiography, i.e. blood column detection, or more recently C.A.T. (Computerized Axial Tomography) and N.M.R. (Nuclear Magnetic Resonance).

In the case of angiography, the detection of the blood column does not always allow the pathology to be detected, by x-ray the evidence of pathology is almost impossible as the prostheses currently available on the market are not radiopaque; on the contrary, by C.A.T. or N.M.R. and by echography a section detection of the pathology is possible even if it is very difficult to detect and quantify any displacement of the prosthesis end from the artery end.

Disclosure of the invention:

The main object of this invention is to overcome the above-mentioned drawbacks by making an internal prosthesis for the substitution of a part of the human body particularly in vascular surgery, which allows the detection of its positioning by means of a simple x-ray apparatus.

Within this scope of the invention, a relevant object of the invention is to design a prosthesis allowing the detection and the quantification of its displacement from the artery to which it was connected.

Another object of the invention is to make a prosthesis which, even if it allows an easier detection, has the same functional properties of the current prostheses.

e above and other objects are fulfilled by means of an internal prosthesis for the substitution of a part of the human body particularly in vascular surgery, having a body with a substantially tubular configuration of plastic material well-tolerated by the human body and being suitable for being associated by its free ends, by means of a cross or oblique suture, to the ends of one or more arteries, characterized in that said body is radiopaque and/or in that said body has radiopaque surface portions developing without discontinuity over its entire surface.

Brief description of the drawing:

Further features and advantages of the invention will be better understood from the description of a preferential embodiment, which is merely illustrative, of the prosthesis in accordance with the invention, shown by way of example and not limited thereto in the enclosed drawings in which:

- Fig.1 shows the various configurations that the prosthesis of the invention may have;
- Fig.2 is a schematic view of the prosthesis suture with an artery according to the well-known technique;
- Fig.3 shows the pathology determined by the detachment of the prosthesis from the artery; and
- Fig.4 shows a variant of the pathology shown in Fig.3.

Ways of carrying out the invention:

With particular reference to the above-mentioned Figures,

the prosthesis in accordance with the invention, globally referred to under the reference number 1, has a body, generally referred to as 2, which generally is made of plastic material tolerated by the human body such as some acrylic resins and some ethylene polymers.

Suitably, according to the type of vascular surgery to be performed, the body 2 has different configurations that are all substantially tubular and that in particular might be also cylindrical, "Y"-shaped, or tapered, as shown by way of example in Figure 1, and that are able to possess among the basic requirements a high degree of elasticity, a good porosity and enough permeability to migrating cells.

Advantageously, in accordance with the invention, the body 2 is also radiopaque so that the vascular surgeon can accurately determine its position relatively to one or more ends 3 of the arteries by means of an x-ray apparatus of standard type and/or while making the angiography.

More in details, the body 2, defining the prosthesis, can be for instance made radiopaque, as we already said, by means of a suitable processing or by coating or inserting in its wall a radiopaque fabric.

In a preferred embodiment, but not limited thereto, the body 2 has radiopaque surface portions developing without discontinuity over its entire surface, more precisely said radiopaque portions, generally referred to as 7, show an

annular development and are preferably but not necessarily defined for example by a filiform element 5 or by a fabric having radiopacity properties.

Suitably, the radiopaque portions 4 are reciprocally equidistant and parallel along the entire development of the body 2 so that the detection of the existing type of pathology can be extremely easy thus allowing the carrying on of any further investigation and of the treatment, if any.

As the prosthesis relatively to the end of the artery or arteries can show a total or partial detachment, as shown for example in Figure 4, causing a pseudoaneurism due to the coming off of the ends of the artery and of the prosthesis, such coming off being filled by an exapanded scar tissue that is not blood-pressure resistent, as it is shown for example in Figure 3, the parallelism and equidistance of the radiopaque portions having an annular development along the entire body 2 allow to determine accurately in which of the above-mentioned cases the prosthesis is relatively to the artery and therefore allow the vascular surgeon to act accordingly.

Advantageously, the radiopaque portions have the same functional properties of the body 2 so that the special nature of the prosthesis is not altered; moreover, the radiopaque portions are sensorially perceptible and more

precisely they are visible to the naked eye so to make the surgeon's task easier during vascular surgery, i.e. during the execution of the anastomosis at the level of one of the radiopaque rings.

Finally, the radiopaque portions can also have a stain different from the stain of the body 2 and/or from each other in order to better stand out on the same.

Furthermore, it shall be specified that beside the radiopaque portions having an annular development, the body 2 can have a filiform element 5a extending along the longitudinal development of the body 2 and its branches.

The operation of the prosthesis in accordance with the invention is evident from what has been described and illustrated herein; in particular, it can be specified that during vascular surgery the surgeon will cut, according to the needs, a prosthesis length just close to one of the radiopaque portions with annular development so that the latter is at the connection with the artery end and allows later the accurate detection of the connection between artery and prosthesis.

In practice, it has been noticed that the prosthesis in accordance with the invention turns out to be extremely advantageous as it allows, by means of a simple x-ray apparatus now existing in all hospital centers, its detection and correct positioning relatively to the artery

to which it was previously connected.

The invention as herein disclosed is subject to many variations and changes all within the scope of the invention; moreover, all details can be replaced by technically equivalent elements.

In practice, all the materials used as well as the size can be of any type according to the needs and to the state of the art.

Claims:

1.- Internal prosthesis for the substitution of a part of the human body particularly in vascular surgery having a body with a substantially tubular configuration of plastic material tolerated by the human body and suitable for being associated by its free ends, by cross or oblique suture, to the ends of one or more arteries, characterized in that said body is radiopaque.

2.- Internal prosthesis for the substitution of a part of the human body particularly in vascular surgery having a body with a subtantially tubular configuration of plastic material tolerated by the human body and suitable for being associated by its free ends, by suture, to the ends of one or more arteries, characterized in that said body has radiopaque surface portions developing without discontinuity over its entire surface.

3.- Prosthesis according to claims 1 and 2, characterized in that said radiopaque portions are defined by a filiform element.

4.- Prosthesis according to claims 1 and 2, characterized in that said radiopaque portions are defined by a fabric.

5.- Prosthesis according to one or more of the preceding claims, characterized in that said radiopaque portions have an annular development.

6.- Prosthesis according to one or more of the preceding

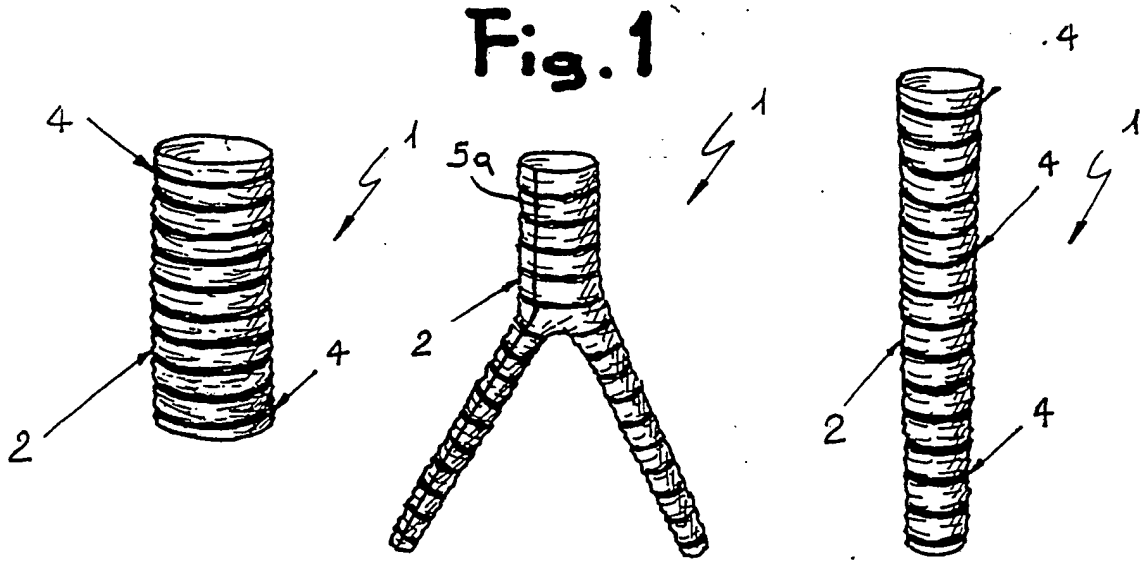
claims, characterized in that said radiopaque portions are reciprocally equidistant and parallel along the entire development of said body.

7.- Prosthesis according to one or more of the preceding claims, characterized in that said radiopaque portions have the same functional properties of said body.

8.- Prosthesis according to one or more of the preceding claims, characterized in that said radiopaque portions are sensorially perceptible.

9.- Prosthesis according to one or more of the preceding claims, characterized in that said radiopaque portions have a stain different from the stain of said body and/or from each other.

Fig.1



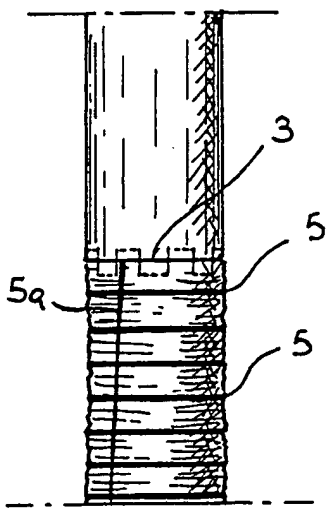


Fig.2

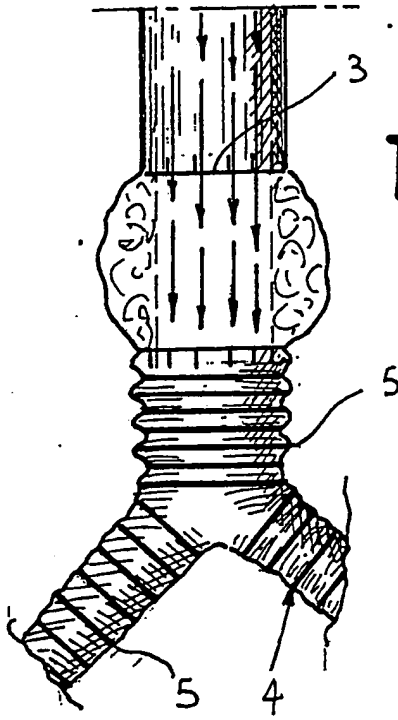


Fig.3

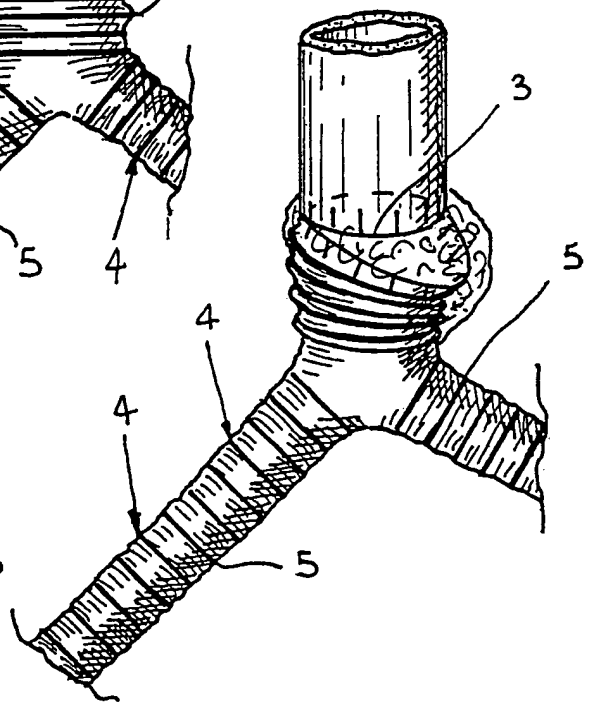


Fig.4

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 :		(11) International Publication Number: WO 88/ 06026
A61F 2/06	A3	(43) International Publication Date: 25 August 1988 (25.08.88)

(21) International Application Number: PCT/EP88/00115

(22) International Filing Date: 17 February 1988 (17.02.88)

(31) Priority Application Number: 19405 A/87

(32) Priority Date: 17 February 1987 (17.02.87)

(33) Priority Country: IT

(71)(72) Applicant and Inventor: ARPESANI, Alberto [IT/IT]; Piazza S. Angelo, 1, I-20121 Milano (IT).

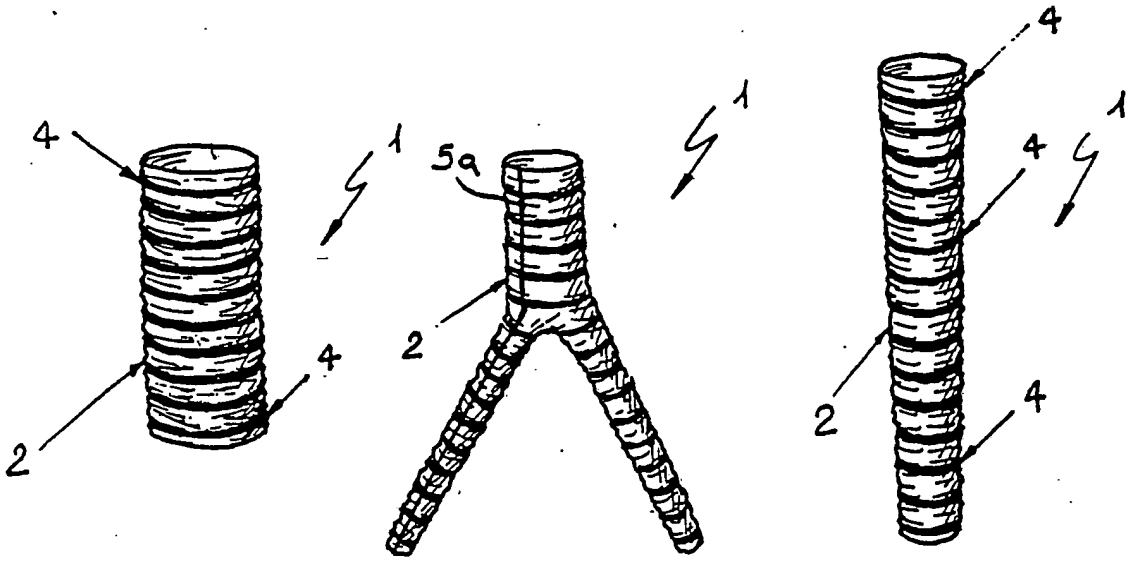
(74) Agent: RAPISARDI, Mariacristina; Studio Tecnico Legale Rapisardi, Largo V Alpini 15, I-20145 Milano (IT).

(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(88) Date of publication of the international search report:
6 October 1988 (06.10.88)

(54) Title: INTERNAL PROSTHESIS FOR THE SUBSTITUTION OF A PART OF THE HUMAN BODY PARTICULARLY IN VASCULAR SURGERY



(57) Abstract

Internal prosthesis for the substitution of a part of the human body particularly in vascular surgery, which has a body (2) with a substantially tubular configuration, made of plastic material tolerated by the human body and suitable for being associated by its free ends, through a suture, to the ends of one or more arteries; advantageously the body defining the prosthesis is radiopaque so that it can be easily detected by means of an X-ray apparatus.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria
AU	Australia
BB	Barbados
BE	Belgium
BG	Bulgaria
BR	Brazil
CF	Central African Republic
CG	Congo
CH	Switzerland
CM	Cameroon
DE	Germany, Federal Republic of
DK	Denmark
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
HU	Hungary
IT	Italy
JP	Japan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
LI	Liechtenstein
LK	Sri Lanka
LU	Luxembourg
MC	Monaco
MG	Madagascar
ML	Mali
MR	Mauritania
MW	Malawi
NL	Netherlands
NO	Norway
RO	Romania
SD	Sudan
SE	Sweden
SN	Senegal
SU	Soviet Union
TD	Chad
TG	Togo
US	United States of America

INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 88/00115

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 F 2/06

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 F; A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	US, A, 4130904 (WHALEN) 26 December 1978 see column 2, lines 5,6 and 49-51	1-3,8
Y	--	5-7,9
Y	FR, E, 1199110 (BODIN, GIRIN & CIE.) 26 December 1960 see page 1, right-hand column, lines 29-35; figures	5-7,9
A	-- US, A, 3839743 (SCHWARCZ) 8 October 1974 see column 3, lines 36-38	4
A	-- US, A, 3657744 (ERSEK) 25 April 1972 see column 2, lines 56-59; figure 2	4
A	-- Life Support, Proc. ESAO, 1-3 September 1982, (Brussels, BE), D. Maass et al.: "Transluminal implantation of intravascular "Double-Helix" spiral prostheses: technical and biological considerations", pages 252-258 see page 252, lines 24-30	1-3

./.

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
11th August 1988	06 SEP 1988
International Searching Authority: EUROPEAN PATENT OFFICE	Signature of Authorized Officer: P.C.G. VAN DER PUTTEN

International Application No. PCT/EP 88/00115

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category*	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	FR, A, 2513111 (GIRAULT) 25 March 1983 see page 4, lines 1-5 --	1-3,5
A	US, A, 4202349 (JONES) 13 May 1980 --	
A	US, A, 4277389 (SCHEETZ) 7 July 1981	

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. EP 8800115 SA 20624

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 30/08/88 The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4130904	26-12-78	None	
FR-A- 1199110		None	
US-A- 3839743	08-10-74	None	
US-A- 3657744	25-04-72	None	
FR-A- 2513111	25-03-83	None	
US-A- 4202349	13-05-80	None	
US-A- 4277389	07-07-81	None	